2. Form G–FIN–4 is amended to revise Item 5, Item 17 and the general instructions to read as follows:

Note: The text of Form G–FIN–4 does not appear in the Code of Federal Regulations.

Form G–FIN–4—Disclosure Form for Person Associated with a Financial Institution Government Securities Broker or Dealer:

Item 5

Item 17

General Instructions

* * * * *

In Item 5, ''Federal Home Loan Bank Board'' is deleted and ''Director, Office of Thrift Supervision'' is added so that the modified question reads: ''To be filed with the following (indicate one): Board of Governors of the Federal Reserve System * * * Comptroller of the Currency * * * Federal Deposit Insurance Corporation * * * Director, Office of Thrift Supervision * * * Securities and Exchange Commission.''

In Item 17, Definitions, the term ''Foreign Financial Regulatory Authority'' is added with the following meaning: ''Foreign Financial Regulatory Authority—Includes any (A) foreign securities authority; (B) other governmental body or foreign equivalent of a self-regulatory organization empowered by a foreign government to administer or enforce its laws relating to the regulation of investment or investment-related activities; or (C) membership organization, a function of which is to regulate the participation of its members in the activities listed above.''

Item 17.A., ''in a domestic or foreign court'' is added so that the modified question reads: ''Have you, within the 10 years preceding the date of this filing, been convicted of or plead guilty or nolo contendere (''no contest'') in a domestic or foreign court to:''

Item 17.B., ''domestic or foreign'' is added so that the modified question reads: ''Has any domestic or foreign court ever:''

Item 17.C.(5) is added to read as follows: ''(5) imposed a civil money penalty on you, or ordered you to cease and desist from any activity?''

Item 17.D., ''foreign financial regulatory authority'' is added so that the modified question reads: ''Has any other federal regulatory agency, any state regulatory agency or foreign financial regulatory authority ever:''

Item 17.F., ''other than as reported in Items 17.A., B., or D.'' is added so that the modified question reads: ''Has any foreign government, court, regulatory agency, or exchange ever entered an order against you related to investments or fraud other than as reported in Items 17.A., B., or D.?''

In the general instructions to Form G-FIN–4, Items 3.b., 3.c., and 3.d. are revised to read as follows:

3.b. ''The Board of Governors of the Federal Reserve System, in the case of a State member bank of the Federal Reserve System, a foreign bank, an uninsured State branch or State agency of a foreign bank, a commercial lending company owned or controlled by a foreign bank (as such terms are used in the International Banking Act of 1978), or a corporation organized or having an agreement with the Board of Governors of the Federal Reserve System pursuant to section 25 or section 25A of the Federal Reserve Act;''

3.c. ''The Federal Deposit Insurance Corporation, in the case of a bank insured by the Federal Deposit Insurance Corporation (other than a member of the Federal Reserve System or a Federal savings bank) or an insured State branch of a foreign bank (as such terms are used in the International Banking Act of 1978);''

3.d. ''The Director of the Office of Thrift Supervision, in the case of a savings association (as defined in section 3(b) of the Federal Deposit Insurance Act) the deposits of which are insured by the Federal Deposit Insurance Corporation; and''

Dated: April 3, 1995.

Frank N. Newman,

Deputy Secretary.

[FR Doc. 95–9056 Filed 4–12–95; 8:45 am]

BILLING CODE 4810–39–W

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 87C–0316]

Listing of Color Additives Exempt From Certification; Astaxanthin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of astaxanthin as a color additive in the feed of salmonid fish to enhance the color of their flesh. This action is in response to a petition filed by Hoffmann-La Roche, Inc.

DATES: Effective May 16, 1995, except as to any provisions that may be stayed by the filing of proper objections; written objections and request for a hearing by May 15, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3078.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the Federal Register of December 2, 1987 (52 FR 45867), FDA announced that a color additive petition (CAP 7C0211) had been filed by Hoffmann-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110–1199. The petition requested that the color additive regulations in part 73 (21 CFR part 73) be amended to provide for the safe use of astaxanthin as a color additive in the feed of salmonid fish. The petition was filed under section 706(d) (now section 721(d)) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376(d) (now 379e(d)).

II. Safety of the Petitioned Use

Astaxanthin is 3, 3′-dihydroxy-β, β-carotene-4, 4′-dione. Pure crystalline astaxanthin must be stored in the absence of light, heat, and oxygen to minimize chemical changes and decomposition that would result in loss of color. Thus, it is necessary to produce a stabilized form of astaxanthin for it to be marketed for addition to salmonid feed for the purpose of coloring the fish flesh.

The petitioner manufactures crystalline astaxanthin in a stabilized beadlet form and has presented evidence in the petition to establish the length of the shelf-life of this beadlet. Under § 70.25(a)(4) (21 CFR 70.25(a)(4)), expiration dates for the product in sealed and open containers must be stated on the label of a color additive. FDA finds that, given the concerns about shelf life, the expiration dates are a material fact that must be disclosed on the label of the product under sections 201(n) and 403(a)(1) of the act (21 U.S.C. 321(n) and 343(a)(1).

Astaxanthin occurs in the flesh of wild salmon at levels ranging from about 4 to 34 parts per million and is responsible for its pink or red coloration (Ref. 1). Wild salmon consume astaxanthin as a component of their natural diet and deposit a portion of the astaxanthin unchanged in their flesh

(Ref. 2). The amount of astaxanthin that FDA is permitting for use in finished feed (80 milligrams per kilogram (mg/kg), 72 grams (g) per ton) (§ 73.35(c)(2)) will result in depositions of the color additive in the flesh that will produce a coloration comparable to that in the flesh of wild salmon. This conclusion is supported by the similar values reported for astaxanthin levels in the flesh of aquacultured salmon used in the pigmenting experiments in the petition and in the flesh of wild salmon (Ref. 2). FDA has estimated that this level of astaxanthin in fish flesh, whether caught in the wild or aquacultured, will result in a mean consumer exposure of 15 micrograms/person/day (µ/p/d) and a 90th percentile exposure of 29 µ/p/d.

FDA has evaluated the data in the petition and other relevant information on astaxanthin and concludes that the petitioned use of the color additive is safe. This conclusion is based on the following facts: (1) The very small amount of astaxanthin deposited in salmonid flesh that will result from the petitioned use; (2) synthetic astaxanthin differs only in its optical isomeric distribution from astaxanthin present in the flesh of wild salmon; and (3) human exposure to astaxanthin from consumption of aquacultured salmon fed synthetic astaxanthin is comparable to the exposure to astaxanthin from wild salmon. In addition, the petitioner has submitted results from short-term and long-term toxicity studies using synthetic astaxanthin. The results of these studies support the conclusion that there is a reasonable certainty of no harm from the petitioned use of astaxanthin (Ref. 3).

FDA is adopting an identity and specifications for the color additive in § 73.35(a) and (b) to characterize the additive that has been evaluated and to ensure its safe manufacture and use.

III. Comments on the Petition

Beginning in late 1992, FDA received a total of 21 letters that were submitted as comments on the petition. One comment from a State agency and one comment from a trade association endorsed the petitioned use of astaxanthin. A manufacturer of *Phaffia* yeast, a source of astaxanthin used in some foreign countries, submitted a series of five comments containing considerable information on *Phaffia* yeast and requested that the agency also grant approval for this source, and all other safe and suitable sources, of astaxanthin. The comment also requested that FDA grant authority for other parties to make independent determinations that other sources of astaxanthin may be considered safe and suitable sources of the color additive for use in aquaculture.

The remaining 14 comments from a trade association, a foreign national organization, 4 commercial companies, and 8 academic and research institutes, generally supported the view that the regulation for astaxanthin should be written to include all safe and suitable sources of the color additive. One of the comments requested that the regulation listing astaxanthin for use in salmonid feed be written to include the comment's strain of *Phaffia* yeast as a source of astaxanthin.

As justification for these requests, the comments asserted that there should be no safety concerns with the use of astaxanthin for coloring the flesh of fish because astaxanthin occurs in nature, coloring the flesh of wild salmonids, and also because it occurs in a variety of sources in nature that are consumed without harm as food by wild fish and other wild animals. The comments also suggested that it would be advantageous to the aquaculture# industry to be able to use as many sources of astaxanthin as possible, and that it would be an efficient use of the industry and FDA's resources if petitions for these products did not have to be submitted and reviewed individually by the agency. In the event that FDA was unable or unwilling to expand the final regulation as requested, one comment requested that the agency modify the specifications for astaxanthin requested by the petitioner to authorize the use of other sources of astaxanthin, including the source of astaxanthin used by the comment. The comment specifically requested that the proposed specifications for astaxanthin be modified to include a higher percentage of the *cis* isomer and a 10-fold increase in carotenoids other than astaxanthin.

FDA has reviewed these comments and finds that two of the comments fully support the petition, and that none of the comments has raised concerns about the safety of astaxanthin or about its technical effectiveness for the petitioned use. Thus, the agency concludes that all the comments fully support FDA's conclusions regarding the safety of astaxanthin for the petitioned use.

FDA has considered whether it should expand the scope of the listing regulation to include *Phaffia* yeast and other materials containing astaxanthin. The regulation set forth below does not specify the source of astaxanthin or the manufacturing process because the agency has made its safety determination based on the chemical similarity of synthetic astaxanthin to astaxanthin from natural sources. Therefore, any source could be used to produce the color additive as long as the astaxanthin meets the identity, specifications, and stability requirements defined in § 73.35, and it is manufactured in accordance with good manufacturing practice. However, the specifications are listed to convey the fact that FDA has evaluated only a particular form of the color additive.

Several of the comments have requested that they be allowed to use a product derived from an organism such as *Phaffia rhodozyma* as a color additive without isolating the astaxanthin. Thus, they wish to market a biomass product that contains only a small amount of astaxanthin with the rest of the material being residues from the organism. The agency is concerned that deleterious materials may be included in fish feed from these sources because they are not found in the habitat of salmonids. Thus, interested parties should submit information supporting the safety of these products, and that they perform their intended effect, in the form of a new color additive petition to demonstrate that provision for these materials should be made in § 73.35.

FDA also concludes that it cannot expand the scope of this petition because an expanded review would require additional time to evaluate the safety and suitability of other materials containing astaxanthin. Such a review would cause an avoidable delay in the issuance of a final rule for the petitioned use of the color additive. FDA believes that such a delay would be unfair to the petitioner. The petitioner has stated that it would be unwilling to acquiesce in such a delay. Any such delay could cause significant economic loss to the petitioner and could be responsible for a significant delay in the use of astaxanthin by the United States aquaculture industry. Thus, FDA concludes that it is appropriate to require that those parties who wish to use astaxanthin products that do not comply with the listing regulation submit their own color additive petitions for such use.

Regarding the requested modifications in the specifications for astaxanthin, the agency cannot include the 10-fold increase in carotenoids other than astaxanthin in the regulation because a color additive with such a broad specification could be substantially different from the astaxanthin that the agency evaluated for safety.

Regarding the comment on allowing a higher percentage of *cis* isomers, astaxanthin can exist as different geometric isomers, known as *cis*- or *trans*-isomers. In the *cis* configuration, the largest functional groups on either

end of a double bond are on the same side of the molecule. In the *trans* configuration, they are on the opposite sides of the molecule. In the case of astaxanthin, there are nine double bonds that can have *cis* or *trans* configurations to give a bent or nearly linear molecular geometry. These isomers can be easily interconverted to give an equilibrium mixture.

The requested specification for the *cis*-astaxanthin level is unnecessary because no safety concerns have been demonstrated with regard to the proportions of the *cis* and *trans* isomers of astaxanthin. Furthermore, the isomeric forms are readily interconverted (Ref. 1), occur in wild salmon, and color the flesh of salmonids. There is no evidence to suggest that the ratio of isomeric forms would affect the safety of astaxanthin. The proportion of *cis*/*trans* isomers of astaxanthin in the petitioned color additive lies within the range of the ratios found in astaxanthin extracted from the flesh of wild salmon (Ref. 4). Therefore, the regulation presented below does not contain a specification for the amount of *cis*-astaxanthin.

IV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Schiedt, K., F. J. Leuenberger, and M. Vecchi, ''Natural Occurrence of Enantiomeric and meso-Astaxanthin,'' *Helvitica Chimica Acta*, 64:449–457, 1981.

2. Meyers, S. P., and H-M Chen, ''Astaxanthin and its Role in Fish Culture,'' From The Proceedings of Warmwater Fish Culture Workshop. Special Publication No. 3, pp. 153–165, 1992.

3. Welsh, J. J., Memorandum entitled ''Final Toxicology Memo on CAP 7C0211 (Astaxanthin in Fish Feed)'' from the Additives Evaluation Branch (HFS–227) to the Direct Additives Branch (HFS–217), Center for Food Safety and Applied Nutrition, FDA, May 26, 1993.

4. Turujman, S. A., ''Rapid Direct Resolution of the Stereoisomers of All-*trans* Astaxanthin on a Pirkle Covalent L-Leucine Column,'' *Journal of Chromatography*, 631:197 (abstract), 1993; Poster presented at the 106th Annual AOAC International Meeting, Cincinnati, OH, August 31 to September 3, 1992.

V. Conclusions

FDA has evaluated the data in the petition and other relevant material and concludes that astaxanthin that meets the specifications in § 73.35(b) is safe and suitable for use in salmonid feed to pigment their flesh, and that part 73 should be amended as set out below. In addition, based upon the factors listed in § 71.20(b) (21 CFR 71.20(b)), the agency concludes that certification of astaxanthin is not necessary for the protection of the public health. To ensure its safe use, FDA has limited the amount of astaxanthin that can be incorporated into the finished fish feed to 80 mg/kg (72 g/ton).

To prevent economic fraud in salmonid fish containing added astaxanthin, the regulation requires declaration of the presence of the color additive in accordance with §§ 101.22(k)(2), 101.100(a)(2), and 501.4 (21 CFR 101.22(k)(2), 101.100(a)(2), and 501.4) for labeling of bulk foods. Section 501.4 is referenced in § 73.35(d)(2) to ensure that the presence of astaxanthin in the fish feed will be declared on the ingredient label. Sections 101.22(k)(2) and 101.100(a)(2) are referenced in § 73.35(d)(3) to ensure that, at the retail level, the presence of astaxanthin in the fish will be declared, and that the labeling of the bulk fish container, including a list of ingredients on the container or a counter card with similar information, will be displayed, respectively. Several examples are given in § 101.22(k)(2) for an acceptable statement of declaration of the presence of astaxanthin, e.g., ''Artificial Color,'' ''Artificial Color Added,'' or ''Color Added.''

VI. Inspection of Documents

In accordance with § 71.15(a) (21 CFR 71.15(a)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition (address above) by appointment with the information contact person listed above. As provided in § 71.15(b), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VII. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m. Monday through Friday.

VIII. Objections

Any person who will be adversely affected by this regulation may at any time on or before May 15, 1995, file with Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the Federal Register.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR 21 part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: Secs. 201, 401, 402, 403, 409, 501, 502, 505, 601, 602, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e).

2. New § 73.35 is added to subpart A to read as follows:

§ 73.35 Astaxanthin.

(a) *Identity*. (1) The color additive astaxanthin is 3, 3′-dihydroxy-β, β-carotene-4, 4′-dione.

(2) Astaxanthin may be added to the fish feed only as a component of a

stabilized color additive mixture. Color additive mixtures for fish feed use made with astaxanthin may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Astaxanthin shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Physical state, solid.
0.05 percent solution in chloroform, complete and clear.
Absorption maximum wavelength 484–493 nanometers (in chloroform).
Residue on ignition, not more than 0.1 percent.
Total carotenoids other than astaxanthin, not more than 4 percent.
Lead, not more than 5 parts per million.
Arsenic, not more than 2 parts per million.
Mercury, not more than 1 part per million.
Heavy metals, not more than 10 parts per million.
Assay, minimum 96 percent.

(c) *Uses and restrictions.* Astaxanthin may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of color additive in feed is such that the color additive shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements.* (1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing astaxanthin shall be declared in accordance with §§ 101.22(k)(2) and 101.100(a)(2) of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

Dated: April 10, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–9178 Filed 4–12–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 178

[Docket No. 91F–0465]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of an aqueous solution of citric acid, disodium ethylenediaminetetraacetate (disodium EDTA), sodium lauryl sulfate (SLS), and monosodium phosphate as a sanitizing solution to be used on food-processing equipment and utensils, including dairy-processing equipment. This action responds to a petition filed by Gycor International, Ltd.

DATES: Effective April 13, 1995; written objections and requests for a hearing by May 15, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3083.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of January 3, 1992 (57 FR 291), FDA announced that a food additive petition (FAP 2B4301) had been filed by Gycor International Ltd., c/o Hogan & Hartson, 555 13th St. NW., Washington, DC 20004. The petition proposed that the food additive regulations be amended in § 178.1010 *Sanitizing solutions* (21 CFR 178.1010) to provide for the safe use of of citric acid, disodium EDTA, SLS, and monosodium phosphate as components of a sanitizing solution intended for general use on food-contact surfaces. The petitioner subsequently amended the petition to limit use of the sanitizer on only food-processing equipment and utensils, including dairy processing equipment.

I. Safety and Functional Effect of Petitioned Use of the Additives

Sanitizing solutions are regulated as mixtures of chemicals that function together to sanitize food-contact surfaces. Each listed component in a sanitizing solution has a functional effect, and the agency evaluates the data submitted in support of the efficacy of the entire sanitizing solution. In addition, FDA regulations permit the addition to a sanitizing solution of any substance that is generally recognized as safe (GRAS) for use in food (§ 178.1010(b)). The subject sanitizing solution is an aqueous solution of citric acid, disodium EDTA, SLS, and monosodium phosphate. The function of these components and the basis for FDA's determination of the safety of these components in the subject sanitizer are described below.

A. Citric Acid

Citric acid functions as an antimicrobial agent in the subject sanitizing solution. Citric acid is listed as GRAS for use in human food under 21 CFR 182.1033. FDA regulations permit the addition to a sanitizing solution of any substance that is GRAS for use in food. On the basis of the data submitted in support of the already-regulated uses of citric acid, and the data contained in the food additive petition submitted in support of this sanitizing solution, FDA finds that the use of citric acid in the subject sanitizing solution is safe (Ref. 1).

B. Disodium Ethylenediaminetetraacetate

Disodium EDTA functions as a chelator in the subject sanitizing solution. Disodium EDTA is regulated as a direct food additive under 21 CFR 172.135. On the basis of the data submitted in support of the already-regulated uses of disodium EDTA and the data contained in the food additive petition submitted in support of this sanitizing solution, FDA finds that the use of disodium EDTA in the subject sanitizing solution is safe (Ref. 1).

C. Sodium Lauryl Sulfate

SLS functions as a surfactant in the subject sanitizing solution. SLS is present in regulated sanitizing solutions under § 178.1010(b)(3), (b)(10), and (b)(37). On the basis of the data submitted in support of the already-regulated uses of SLS and the data contained in the food additive petition submitted in support of this sanitizing solution, FDA finds that the use of SLS in the subject sanitizing solution is safe (Ref. 1).